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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,685

07/03/2003

Yehoshua Shachar

7408

79782

7590

01/23/2009

Law Offices of Daniel L. Dawes

5200 Warner Blvd, Ste. 106

Huntington Beach, CA 92649

EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

01/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/614,685

## Applicant(s)

SHACHAR, YEHOOSHUA

## Examiner

ANDREW M. GILBERT

## Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-39 and 41-61 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9,10,12-16,18,21,24,25,28-30,32,37-39,41-43,47,51 and 55-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims **withdrawn** from consideration are 7, 8, 17,19,20,23,26,27,31,34-36,44-46,48-50,52-54 and 58-61.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/3/2008 has been entered.

### ***Acknowledgments***

1. This office action is in response to the reply filed on 12/3/2008.
2. Claims 1, 3-6, 9, 10, 12-18, 21, 22, 24, 25, 28-30, 32, 37-39, 41-43, 47, 51, and 55-57 are pending. The other claims are previous withdrawn or cancelled.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3, 5, 6, 12-16, 18, 22, 24, 25, 28, 29, 32, 33, 37, 38, 39, 41, 42, 43, 47, 48, 51, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan et al (6206914) in view of Patterson (6379323) in further view of Marshall et al (6479052). Soykan et al discloses an implantable apparatus comprising: an implantable pouch (col

3, Ins 6-31; col 8, Ins 63-67; col 9, Ins 38-60; col 10, Ins 4-8; col 12, Ins 51-65; col 13, Ins 16-28; col 14, Ins 26-39; col 15, Ins 5-12; col 16, Ins 23-27, Ins 42-61) having multiple collapsible chambers composed of a bioabsorbable material, the pouch comprising a scaffolding (col 9, Ins 9-37; wherein the stent is disclosed as being polymeric and bioabsorbable; furthermore, see response to arguments below) capable of degrading over time, and a synthetic skin or enclosing the pouch; and multiple medicating agents disposed in said collapsible chambers (col 4, Ins 18-32; col 8, Ins 56-67, col 9, Ins 35-37; col 9, Ins 38-59, col 12, Ins 51-65; wherein each of the microscopic containment vehicles forms a chamber and each of the containment vehicles is capable of containing various cells and therapeutic agents); multiple implantable piezoelectric pumps (col 4, Ins 18-32; col 12, Ins 51-65; col 13, Ins 16-27; col 14, Ins 26-39) fabricated in the pouch which forms a skeleton of the pumps, the pumps being configured to transfer medicating agents to said patient (col 4, Ins 18-32; col 12, Ins 51-65; col 13, Ins 16-27; col 14, Ins 26-39); and an implantable, biocompatible and bioabsorbable skin (col 9, Ins 38-60, col 10, Ins 4-col 11, Ins 14) covering the pouch and pumps; and an implanted control circuit housed within the pouch (col 4, Ins 18-32, col 13, Ins 16-27, col 14, Ins 10-39, col 15, Ins 4-24, col 16, Ins 18-61; Fig 2a; Fig 5; also, Response to Arguments below) to control proper dosing and scheduling of said medicating agent in a closed loop control mode so that control of the operation of the system is performed autonomously as determined by locally sensed homeostatic parameters (col 3, Ins 6-31; col 8, Ins 63-67; col 9, Ins 38-60; col 10, Ins 4-8; col 12, Ins 51-65; col 13, Ins 16-28; col 14, Ins 26-39; col 15, Ins 5-12; col 16, Ins 23-27, Ins 42-61).

5. In reference to claims 3, 5, 6, 12-16, 18, 22, 24, 25, 28, 29, 32, 33, 37, 38, 39, 41, 42, 43, 47, 48, 51, 55, 62-64 see (col 3, lns 6-31; col 5, lns 55-59; col 8, lns 63-67; col 9, lns 38-60; col 10, lns 4-8; col 12, lns 51-65; col 13, lns 16-28; col 14, lns 26-39; col 15, lns 5-12; col 16, lns 23-27, lns 42-61; discussion below in Response to Arguments; wherein the Examiner notes that the device of Soykan et al is fully capable of being placed in at a tumor cite and the sensing elements are fully capable of measuring pressure, temperature, pH, and various physiological properties that can be representative of the state of the tumor site to control agent release and furthermore the drug-eluting cells may be genetically engineered to produce a variety of therapeutic agents (col 8, lns 19-27; additionally the Examiner notes that a pleiotrophic agent is merely an agent that produces many effects and Soykan et al discloses many agents that produce many effects in the body; furthermore, a biomodulator is simply any agent that has elicits a biological response).

6. However, Soykan et al fails to teach collagen matrix scaffolding. Patterson teaches that it is known to have a scaffolding composed of collagen forming a matrix capable of degrading over time (col 4, lns 28-51) for the purpose of maintain the device in a certain position in the body during treatment and then degrading to avoid surgical risks associated with removing the device after treatment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric scaffolding as taught by Soykan et al with the collagen matrix scaffolding as taught by Patterson for the purpose of maintain the device in a certain position in the

body during treatment and then degrading to avoid surgical risks associated with removing the device after treatment.

7. However, Soykan et al in view of Patterson fails to teach a porous matrix of fibers of cross-linked tendon collagen and a chondroitin sulfate with a layer made of synthetic polysiloxane polymer. Marshall et al teaches that it is known to have a porous matrix of fibers of cross-linked tendon collagen and a chondroitin sulfate with a layer made of synthetic polysiloxane polymer (col 7, lns 19-35) for the purpose of providing a matrix scaffolding for an implant that promotes healing and infiltration of fibroblasts, capillaries, and other natural body healing responses. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric scaffolding as taught by Soykan et al in view of Patterson with the Integra<sup>TM</sup> scaffolding as taught by Marshall et al for the purpose of a matrix scaffolding for an implant that promotes healing and infiltration of fibroblasts, capillaries, and other natural body healing responses.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4, 9, 10, 21, 30, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan et al in view of Humes et al (2002/0090388). Soykan et al

discloses the invention substantially as claimed except for expressly disclosing delivering cytokine, chemotherapeutic agents to eliminate tumors. Humes et al teaches that it is known to have a drug delivery device delivering cytokine, chemotherapeutic agents ([011], [074], [075]) for the purpose of tumor elimination. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the agents as taught by Soykan with the cytokine and chemotherapeutic agents as taught by Humes et al for the purpose of delivering therapeutic agents for the purpose of tumor elimination.

***Response to Arguments***

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

11. Further, the Applicant argues that Soykan et al disclose or does not properly suggest:

- i. Collapsible chambers.
- ii. An implanted circuit housed within the pouch.

12. In response to the applicant's argument (i) the Examiner notes that the Applicant has not structurally defined the multiple chambers. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., collapsible chambers timed to coincide with the depletion of the medicating agent inside the chambers) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988

F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, the applicant has not provided any structural detail except for “collapsible” and has not provided a limitation as to the extent or degree of collapsing. The Examiner notes that Soykan et al can read on the limitation in several manners: 1) when the control applies electrical stimulation to the device the microscopic containment vehicles respond by changing shape and releasing medicament; 2) when the device degrade over time, the chambers inherently collapse.

13. In response to the applicant’s argument (ii), the Examiner notes that Fig 2A explicitly show circuitry maintained on the implanted device controlling the pumps for dosing and scheduling (see further Fig 5 and discussion contained in above citations).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/

Examiner, Art Unit 3767

/Kevin C. Simmons/

Supervisory Patent Examiner, Art Unit 3767